DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

September 15, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 48-04

Ray Albers
Owner
Heritage Dairy
13744 Milliken Ave.
Ontario, CA 91761

Dear Mr. Albers:

Our records reflect you are the owner of Heritage Dairy located at 13744 Milliken Ave, Ontario, CA. An investigation of your dairy operation conducted by our investigator on July 20-27, 2004, confirmed that you offered animals for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (henceforth the "Act").

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. The presence of a drug at levels above the established tolerance in edible animal tissue causes the food to be adulterated within the meaning of Section 402(a)(2) of the Act. A food is further adulterated under Section 402(a)(4) of the Act if it has been held under insanitary conditions whereby it may have been rendered injurious to health. Food from animals held under conditions that are inadequate to prevent medicated animals bearing potentially harmful drug residues from entering the food supply are adulterated within the meaning of Section 402(a)(4).

On or about January 12, 2004, you sold a culled dairy cow identified by USDA Laboratory report 427914 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of penicillin in the kidney at 0.66 parts per million (ppm). A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle [21 CFR 556.510].

Secondly, on or about January 28, 2004, you sold a culled dairy cow identified by USDA Laboratory report 427927 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of penicillin in the kidney at 0.93 ppm and in the liver at 0.10 ppm.

Additionally, on or about May 7, 2004, you sold a culled dairy cow identified by USDA Laboratory report 373265 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of penicillin in the kidney at 0.27 ppm.

Our investigation also found that you hold animals under improper conditions whereby diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for the appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are considered adulterated under Section 402(a)(4) of the Act.

It was further determined that you are using drugs in a manner contrary to their approved labeling. Such extra-label use is not permitted, except by or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and in compliance with the limitations set forth for specific extra-label uses [21 CFR 530.10 and 530.11]. Your use of drugs in any manner other than as labeled causes those drugs to be adulterated under Section 501(a)(5) of the Act because the drugs are unsafe under Section 512(a) of the Act..

- You are adulterating injectable penicillin G procaine that you use on dairy cattle in a manner contrary to the approved labeling. The labeled dose is 1 cc per 100 pounds of body weight. Your use of 20-25ccs for cows weighing approximately 1100 pounds is in excess of the labeled directions.

Unless explicitly directed by a licensed veterinarian under a valid veterinarian-client-patient relationship, it is a violation of the law for any person to use any animal drug, in any manner other than at labeled. This is true regardless of whether or not such use results in an illegal drug residue. The FDA is concerned not only about the indiscriminant use of drugs but also the long term ramifications of such use, especially when such use is not in agreement with the approved labeled direction.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operations and the food you distribute are in compliance with the law.

Please note that it is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse which ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should take prompt action to correct the above violations and to assure that the procedures you have established will prevent their recurrence. Failure to do so may result in regulatory action, such as injunction, without further notice. This letter constitutes official notification under the law and provides you an opportunity to correct the violations.

Please advise this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step that has been taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which such corrections will be made. If you have any questions or need clarifications regarding this letter prior to your written response, you may contact Barbara Rincon, Compliance Officer at telephone number (949) 608-4439.

Your written response should be directed to:

Pamela B. Schweikert
Director, Compliance Branch
U.S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

Sincerely,

Monica R Maxwell for

Alonza E. Cruse
District Director